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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/278,601	07/21/94	KNIPE D	DFCI363A

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EXAMINER	
CAPUTA,A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 08/278,601	Applicant(s) Knipe et al.
	Examiner Anthony C. Caputa	Group Art Unit 1645

☒ Responsive to communication(s) filed on *29 Dec 1997* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-9, 12-22, 25-27, 29, and 31-41* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-9, 12-22, 25-27, 29, and 31-41* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1645.

2. Applicants amendment was received 12/29/97 and entered as Paper No. 20. Claims 1-9, 12-22, 25-27, 29, and 31-41 are pending.

Claim Rejections - 35 USC § 112

3. Claims 1-3, 5-7, 9, 12-14, 16-20, 22, 25, 26, 31, 32, 33, 34, 36, 37-39, and 41 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the last Office Action

Applicants argue they are entitled to the scope of the claims which encompass a herpesvirus that has a mutation in one or more genes encoding a protein essential for viral genome replication. Applicants arguments are not persuasive. While it would appear the specification discloses that the inactivation of two essential genes (ICP27 and ICP8) resulted in a functional mutant as argued by applicants said disclosure is no sufficient guidance for one skilled in the art to make and use the invention commensurate in scope with these claims.

Since:

1) the specification fails to provide little guidance (i.e. identity of the genes, or working examples) of mutants as ICP 8 and ICP 28 that have the properties as recited (i.e. renders the herpes virus defective, have the ability to effect an antibody shift, etc);

2) the specification discloses herpesvirus mutants that do not have the properties as claimed (e.g. failed to induce an antibody shift -see pages 50 and 51); and/or

3) proteins from herpesvirus essential for replication differ in structure

one skilled in the art would require undue experimentation to practice the broadly claimed invention.

Applicants cite Exhibit A from Fields Virology, Chapter 72 which lists HSV genes, their products, functions, and whether or not they are dispensable for replication in cell culture as support for the claimed invention. Applicants argument is not sufficient to obviate the rejection since Exhibit A is not present with the application. Beyond this applicants argument is not sufficient to obviate the rejection since from other Chapters cited from this book it would appear the publication date is after the filing date of the instant application.

Applicants urge that the specification provides sufficient teachings for one skilled in the art to practice the claimed invention. Applicants state that the specification teach of methods and examples to employ in order to test the other genes. These arguments are not considered persuasive. The decisional law has held the mere recitation in the specification of a broad concept does not necessarily provide a sufficient basis for broadly claiming it. See Ex parte Gardner 157 USPQ 162 (Bd. Pat. Appls and Interf. 1967), In re Cavallilo, 127 USPQ 202 (CCPA 1969). The fact that the terms in a claim are the same as those in the specification does not prevent the claims from being rejected as unduly broad if they define subject matter not define subject matter not described to be the actual invention by means of adequate representative samples. See in re Lund, 153 USPQ 625 (CCPA 1967). In the instant case since:

1) the specification fails to provide little guidance (i.e. identity of the genes, or working examples) of mutants as ICP 8 and ICP 28 that have the properties as recited (i.e. renders the herpes virus defective, have the ability to effect an antibody shift, etc);

2) the specification discloses herpesvirus mutants that do not have the properties as claimed (e.g. failed to induce an antibody shift -see pages 50 and 51); and/or

3) proteins from herpesvirus essential for replication differ in structure

one skilled in the art would require undue experimentation to practice the broadly claimed invention. See *in re Wands*, 858 F.2d 731 8 USPQ2d 1400 (Fed. Cir. 1988) and *Ex parte Maizel* 27 USPQ 2d 1662 (Bd. Pat. App. & Int. 1992) . In view of the foregoing the enablement rejection is maintained.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. The prior rejection of claims 1-3, 5-7, 9, 12-14, 16-20, 22, 25, 26, 31, 32, 33, 34, 36, 37-39, and 41 under 35 U.S.C. 102(a) as being anticipated by Inglis et al. (WO 92/05263-Reference cited by Applicants in IDS Statement) is withdrawn in view of applicants amendment.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-9, 12-22, 25-27, 31- 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inglis et al. (WO 92/05263 Reference provided in Applicants' IDS) and further view of McCarthy et al Journal of Virology 63(1):18-27 1989).

8. Claims 1-9, 12-22, 25, 26, 29, and 31- 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inglis et al. (WO 92/05263 Reference provided in Applicants' IDS) and further view of McCarthy et al Journal of Virology 63(1):18-27 1989).

Inglis et al disclose a mutant virus which has a defect in gene essential for virus production (i.e. gH), whose genome includes genetic material including an immunogenic protein from a pathogen exogenous to said virus. Inglis et al. disclose said virus is a herpes simplex virus. Inglis et al disclose a vaccine comprising said virus (see pages 6, 17-25, 38 and 39). Inglis et al. disclose of vaccinating mice with the HSV-1 mutant in PBS, wherein said mutant has mutation in the gH gene. Inglis et al. further disclose said mutant expressing SIV-gp 120 (see pages 25-37). Inglis et al. does not characterize the method of vaccinating the animal for the intended use as recited. However, the intended use of the claimed invention (i.e. treatment of an immunomodulatory disease) carries no patentable weight. Inglis et al suggests using viral mutants that are inactivated for genes involved in viral genome replication for an immunogenic response (see pages 8-10; especially page 8; line 21 to page 9 line 12). Inglis et al teach the mutant virus can operate in the same way as an conventional killed virus or an attenuated virus (see page 8, lines 9-12). Inglis et al teach the invention can be applied to such virus as herpes viruses where the essential gene can be identified.

Inglis et al does not teach of using a ICP 8 or ICP 27 mutants as recited.

McCarthy et al teaches of HSV-1 ICP27 deletion mutants which were replication incompetent (see abstract).

Guo et al. teach of several mutant herpesvirus of the infected cell protein 8 (ICP 8) which lack the ability to replicate and bind (see abstract, page 5259, Figure 5, and Table 4) . Guo et al. Describes a mutant d301 from HSV which is replication defective.

While Inglis et al does not teach of using a ICP 8 or ICP 27 mutants as recited, since Inglis et al. suggests viral mutants that are inactivated for genes involved in viral genome replication for an immunogenic response and vaccination it would have obvious to one of ordinary

skill in the art that the ICP 27 mutant as set forth McCarthy et al or ICP 8 mutant as set forth by Guo et al would have been useful for vaccination.

Applicants argue the rejection should be withdrawn since Inglis et al. (WO 92/05263) teaches the gene should be preferably one which is later in infection. Applicants argument is not persuasive to obviate the rejection over Inglis et al. suggests using viral mutants that are inactivated for genes involved in viral genome replication for an immunogenic response (see pages 8-10; especially page 8; line 21 to page 9 line 12).

Applicants set forth that a reference by Inglis et al published in 1994 teaches way from using the present invention. Applicants argument is noted. However, one of ordinary skill in the art at the time of the invention would not have been taught away of using the mutated genes in view of the prior art as cited by the Examiner above since the reference by Inglis et al published in 1994 was published **after** the effective filing date of the instant application.

9. Claims 1-9, 12-22, 25-27, 29, and 31- 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed while providing literal support for claiming a mutation in the gene encoding a protein essential for **viral replication** does not provide support or claiming a mutation in the gen encoding a protein essential for **viral genome replication**.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Anthony C. Caputa, whose telephone number is (703)-308-3995. The examiner can be reached on Monday-Thursday from 8:30 AM-6:00 PM. The examiner can be reached on alternate Fridays. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703)-308-0196.

Papers related to this application may be submitted to Art Unit 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The Fax number is (703)-308-4242.

Anthony C. Caputa, Ph.D.
March 30, 1998

ANTHONY C. CAPUTA
PRIMARY EXAMINER